

REMARKS

Reconsideration of the present application is requested. Applicants' response to the prior Office Action was deemed moot in view of new grounds of rejection presented in the current Office Action. This application now includes independent claims 45, 54, 80, 85 and 92, along with several corresponding dependent claims. Each of these claims stand rejected as obvious in view of the combination of the published application of Belef (2002/0147497) and the patent of Powlan (4,888,024).

It is first noted that Applicants have amended claim 45 to clarify certain steps of the claimed method. In particular, the step of "sealably engaging" has been amended to clarify that the step involves not only "sealably engaging" but also "introducing a curable biomaterial", which is consistent with the last step of the claim.

Independent Claim 45 and its dependent claims

Looking first at independent method claim 45, it is believed that the cited combination of references fails to disclose every limitation of that claim and that a *prima facie* case for obviousness has not been established. In particular, claim 45 recites the step of "distracting the vertebral bodies apart to increase disc height." The Belef publication was alleged to disclose this step, with specific reference to FIG. 4B, at page 2 of the Office Action. At page 3 it was stated that with respect to the method claims, the recited steps would be inherently carried out by the device disclosed in Belef. The first error in this analysis rests in the characterization of the Belef device as "capable of engaging endplates ... and distract the vertebrae." Office Action, p. 2. Claim 45 is a method claim, so something more than a mere "capability" of a disclosed device is necessary to support an obviousness rejection.

Moreover, there is nothing in Belef that discloses any such capability. As shown in FIGS. 5 and 7, the devices in Belef are only introduced into the disc annulus. The entire disclosure of Belef describes an opening in the annulus and closing that opening with a plug. See, e.g., "creating an opening in the annulus" (Para. 16, line 7); "securing the plug member into the opening, e.g., by threading the plug member into tissue surrounding the opening" (Para. 0021, lines 7-8); "A plug may be introduced into the

"opening" (Para. 0023, lines 6-7); "The plug may be expandable to engage the annulus fibrosus tissue surrounding the opening" (Para. 0069, lines 6-7). In describing the embodiment shown in FIG. 4B and its use as depicted in FIG. 5, Belef explains that "an opening 95 may be made in the annulus fibrosus 92" (Para. 0082, line 2), "the plug member 314 may be introduced into the opening 95" (Para. 0082, lines 7-8). With respect to the embodiment shown in FIG. 7, Belef states that "the plug 414 is threaded or otherwise engaged within the opening 95" (Para. 0087, lines 7-8).

There is no disclosure in Belef of the plug engaging the endplates of opposing vertebrae. More pertinently, there is no disclosure of distracting vertebrae in Belef, and for that matter the words "distract" or "distraction" never appear in the reference. Consequently, there is absolutely no basis for the statement in the Office Action that the Belef plug shown in FIG. 4B is "capable of engaging endplates ... and distract[ing] the vertebrae." It is noted that Belef does discuss expanding the bladder 12 to force the vertebrae further apart. See, Para. 0063, lines 7-12. However, it is the bladder inside the disc cavity that is expanding, and not the plug 314 shown in FIG. 4B. Applicants have amended claim 45 to explain that the biomaterial is injected into the distracted space which is consistent with the construction applied in the Office Action and which clearly distinguishes over the Belef expandable bladder.

In apparent recognition of the deficiencies of Belef, the entire obviousness rejection of method claim 45 is premised on the statement that "the method steps ... would have been inherently carried out in the operation of the [Belef] device," with specific reference to the step of "distracting the vertebral bodies apart to increase disc height". A review of the patent rules of practice provides no support for an "inherency" argument to support a *prima facie* case of obviousness. See, e.g., M.P.E.P. 2143 enumerating exemplary rationales for a *prima facie* case of obviousness following the U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.* The rules do consider "implicit disclosure" as a proper approach. See, M.P.E.P. 2144.01. Under this approach, "it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *Id.* However, the acceptable "inferences" must be drawn from what is actually disclosed. There is nothing in the Belef reference from which one could "infer"

a completely different use of the plug of FIG. 4B other than in the manner expressly disclosed in that reference.

The principle of "inherency" is discussed with reference to the disclosure in a pending patent application and the ability of the applicant to amend the specification to recite a function, theory or advantage of a device that "inherently performs a function or has a property, operates according to a theory or has an advantage." M.P.E.P.2163.07(a). Thus, in the context of a patent application, the principle of inherency only applies to a function, property, theory of operation or advantage of a device. Pursuant to the M.P.E.P., inherency is not used to establish an entirely different use of a device from what is disclosed in a specification. There is certainly no support for using "inherency" to establish an entirely different use of a device in the prior art from its specifically disclosed use.

There is nothing in the Belef reference that suggests using the plug 314 to distract adjacent vertebral bodies and increase disc height. Moreover, even if the plug 314 of Belef was somehow modified to contact the vertebral endplates (as hypothesized in the Office Action), there is nothing about the structure of the plug that would allow it to function as a distractor. The plug appears to have constant outer and thread root diameters, so that as the plug is threaded into the annulus it cannot spread tissue surfaces apart, as is required for distraction. Consequently, even an inherency argument must fail because the structure disclosed in Belef cannot inherently perform the appointed function, at least not without a hindsight redesign of the plug 314.

The application of "inherency" is not supported by the accepted standards for assessing obviousness following the *KSR* decision. Moreover, there is nothing in the Belef reference to support the alleged inherency. Finally, even if an entirely new method of using the Belef plug is proposed, the structure of the Belef plug still cannot perform the necessary step of distracting to increase disc height called for in Applicants' claim 45. For this reason alone the case for obviousness fails.

Furthermore, claim 45 recites the step of scalably engaging the disc annulus and "introducing under pressure a curable biomaterial .. through said opening contiguously into the intradiscal space." The rejection in view of Belef ignores the term

"contiguously". Belef discloses an inflatable or expandable bladder 312 that is used with the plug as shown in FIGS. 4A-4B. The bladder is filled with the "fill material" disclosed in Belef. See, Paras. 0065, 0075. Thus, in Belef it is the bladder that is contiguous within the intradiscal space, not the "fill material". The term "contiguous" means "in contact with" or "touching". It is clear that in Belef, the "fill material" only touches the bladder 312, and not the disc or intradiscal space. Thus, Belef does not disclose sealably introducing under pressure a curable biomaterial through the annulus opening and contiguously into the intradiscal space, as required by method claim 45. To the extent that the "inherency" argument set out at page 3 of the Office Action is also applied to this missing method step, the arguments set forth above apply with equal force.

The Belef reference fails to disclose at least two elements of Applicants' method claim 45 – the step of distracting to increase disc height and the step of sealably introducing a biomaterial contiguously into the intradiscal space. Since there is no suggestion to modify Belef to meet these limitations, the obviousness rejection was forced to resort to an improper application of "inherency". As explained above, this approach is improper, but at any rate fails to establish a *prima facie* case for obviousness using Belef. It is noted that the intramedullary prosthesis of the secondary reference of Powlan was simply cited as showing the use of a vented O-ring seal, and therefore adds nothing to the method step limitations in question.

Since there is no *prima facie* case for obviousness of claim 45, Applicants request that this rejection be withdrawn. Method claim 45 and its dependent claims 46, 47 and 49-53 are believed to be patentable over the cited art. It is further noted that dependent claims 51-53 include limitations that are not disclosed or suggested in, or implicit in the cited art. Claim 51 recites that the distraction step is performed before the biomaterial is introduced. In Belef, the introduction of the "fill material" is disclosed in one embodiment as sufficient to separate the vertebral bodies. To the extent that this embodiment discloses distraction, it is clear that it is by the introduction of the "fill material" and not prior to that step, as required by claim 51.

Dependent claim 45 defines the distraction step as being performed by a separate distractor. Belef discloses no distractor, other than the inflated bladder and "fill

material", which are of course not separate from themselves. In claim 53, this distractor is disclosed as a cannulated distractor. To the extent that the plug 314 is regarded as a cannulated element, it is not a distractor, as discussed above. Thus, dependent claims 51-53 are believed to be patentable on their own merits.

Independent claim 54 and its dependent claims

Independent claim 54 was also rejected as obvious in view of the combination of Belef and Powlan. The Powlan reference was cited for its disclosure of a "seal having O ring with a vent", although no specific corresponding structure in Powlan was identified. It is presumed that the vent alleged in Powlan is the passageway 22 shown in FIG. 1. As explained in Powlan, air is withdrawn from the flexible membrane 28 through the passageway 22, and then liquid cement is injected under pressure into the membrane through this same passageway. See, col. 3, lines 31-36. Thus, the alleged vent in Powlan is also the "tube" used for the flow of fluent material into the membrane. Consequently, the combination of Powlan with Belef would result in the tube 316 of Belef being used to evacuate the bladder 312 and fill the bladder. Powlan does not disclose a vent that is separate from the fill tube, and neither does Belef. Thus, Powlan actually adds nothing to Belef, unless hindsight reconstruction of the Belef plug is undertaken. Powlan does not disclose adding a separate vent, and neither does Belef. It is only with hindsight that it can be concluded that adding a separate vent to Belef would be obvious.

To the extent that this misconstruction of Powlan and Belef is due to a false reading of claim 54, Applicants have amended this claim to make clear that the vent is separate from the tube used to introduce the fluent material. Again, as discussed above, a separate fill tube and vent is not disclosed in either Powlan or Belef. Thus, the combination of these references still fails to disclose every limitation of claim 54 and therefore cannot render that claim obvious.

It is believed that independent claim 54 and its dependent claims 55-72 are patentable over the art of record. It is noted that dependent claims 60 and 72 define structure for distracting the adjacent vertebrae. As discussed at length above, there is no

disclosure or suggestion in Belef of such distraction, so it is believed that these claims recite further limitations not present in the cited art.

Independent claim 80 and its dependent claims

Applicants have amended independent claim 80 to include the limitations of dependent claim 83, which claim has been cancelled. Thus, claim 80 now includes the limitation of a vent separate from the tube for introducing the fluent material. As discussed above with respect to claim 54, the cited art does not disclose or suggest a separate tube and vent. Thus, it is believed that amended claim 80 and its dependent claims are allowable over the art of record.

Applicants have further amended claim 85 to place it in independent form by incorporating the limitations of unamended claim 80. Claim 85 recites that the extent of the tube is defined by a distal tip that is configured to distract the opposite vertebrae. As discussed at length above, there is no disclosure or suggestion in Belef of the plug 314 being configured to distract. Thus, for reasons discussed above, it is believed that newly independent claim 85 and its dependent claims 86-91 are patentable over the art of record.

It is noted that in the Office Action, the term "configured to" was regarded as having no patentable weight. The allegation that the term "configured to" only implicates function and not structure is not supported in the Office Action. This term most certainly confers structure to an element, namely the structure necessary to distract in the case of claim 85. While it is believed that the "configured to" language in claim 85 is sufficient, Applicants' have amended this limitation to indicate that the distal tip is also "sized" to provide distraction, which also imparts clear structural limitations to the distal tip. When considered in its entirety, claim 85 as amended is patentable over the art of record.

Claims 88 and 89 depend from amended allowable claim 85. The limitations of these claims appear to have been ignored in the Office Action. Claim 88 recites that the kit includes a plurality of differently sized removable distal tips. There is nothing in either Belef or Powlan that discloses or suggests this limitation. In Belef, since the plug 314 is not intended to distract but simply to be introduced into an opening formed in the

annulus, there is no need for different sizes of the plug. The opening formed in the annulus can always be the same diameter so the size of the plug 314 can always be the same. There is no motivation or reason to add differently sized plugs to the Belef device. Thus, claim 88 is believed to be patentable on its own merits.

Claim 89, which depends from claim 85, recites that the distal tip is bioresorbable. In Belef, the liner is disclosed in one embodiment as formed of a bioabsorbable liner material (Para. 0017) and the fill material may include a bioabsorbable material (Para 0085), but the material of the plug 314 is not specifically disclosed. It can be inferred that since threads are cut into the plug it may likely be formed of a biocompatible metal. Notwithstanding such inference, there is nothing in Belef that discloses or suggests that the plug may be formed of a bioresorbable material. It is therefore believed that claim 89 is patentable on its own merits.

#### Independent claim 92 and its dependent claims

Independent claim 92 is a method claim that recites the step of introducing a fluent curable material into the intradiscal space. This step further states that the curable material is introduced "directly into the intradiscal space in contiguity with said annulus fibrosus or remaining nucleus pulposus." As discussed above with respect to claim 45, the term "contiguity" has apparently been ignored or misconstrued in the obviousness rejection of claim 92. In Belef, the "fill material" is in contact with or touches only the bladder 12, 312. The "fill material" in Belef does not touch the disc annulus or any remaining disc nucleus within the intradiscal space. There is nothing implicit or "inherent" in Belef that counteracts the clear disclosure of the "fill material" contacting only the bladder. There is no suggestion in Belef of eliminating the bladder, which would be necessary for Belef to somehow meet the limitations of claim 92. The Powlan reference also discloses a bladder that is expanded and filled by bone cement, and similarly fails to disclose directly introducing the bone cement into contiguity with the surrounding bone.

The cited art fails to disclose or suggest introducing a fluent material directly into the intra discal space in contiguity with the annulus or the remaining nucleus. Any

purported "inherency" argument is both improper and insufficient. There is simply nothing in the cited art that discloses this step of claim 92. Thus, it is believed that claim 92 and its dependent claims 93-97 and 34-44 are patentable over the art of record.

It is further noted that dependent claim 97 adds the step of removing the seal after the injected material has cured. In both Belef and Powlan, all of the structure remains after the fill material or bone cement has cured. As shown in FIG. 5 of Powlan, the "fill material" resides not only within the bladder but also within the plug 314. There is nothing in either Belef or Powlan that contemplates removing either the plug 314 of Belef or the collar 18 of Powlan. Certainly with respect to Powlan, the collar cannot be removed unless the joint prosthesis is also removed. In Belef, removing the plug 314 would require reopening the opening through the disc annulus, which would necessarily incur the risk that the bladder and fill material will herniate through that opening. Since these references fail to disclose the method step of claim 97, this claim is believed to be patentable on its own merits.

Dependent claim 39 adds distraction to the method of claim 92. As discussed above, Belef does not disclose this distraction, so claim 39 should be patentable on its own merits.

Dependent claim 43 adds a vent and claim 44 recites that the biomaterial is introduced into the intradiscal space until it seeps from the vent. As argued above, Powlan does not disclose a vent that is separate from the tube used to introduce the fluent material. The limitation recited in claim 44 regarding "seepage of biomaterial" is not addressed in the Office Action. There is nothing in either Belef or Powlan that discloses or suggests this limitation, especially since only one passageway is provided in both devices. There is no provision for any "seepage" in either Belef or Powlan because the respective fill material or bone cement are introduced through the only passageway available. Since the art of record fails to disclose every limitation of claims 43 and 44, these claims are believed to be patentable on their own merits.

Conclusion

In view of the foregoing arguments it is believed that the rejection of the pending claims has been traversed. The newly cited combination of Belef and Powlan cannot render the pending claims obvious because it fails to disclose every element recited in the claims. There is therefore no motivation or suggestion to modify Belef in the manner necessary to meet the limitations in the pending claims. The argument of "inherency" is both improper and insufficient to establish a *prima facie* case for obviousness. Therefore, it is requested that these rejections be withdrawn and that action be taken toward a Notice of Allowance.

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